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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,869	08/22/2003	J. Frank Koenig	7233	8644
39196	7590	09/01/2005	EXAMINER	
SHLESINGER, ARKWRIGHT & GARVEY LLP 1420 KING STREET SUITE 600 ALEXANDRIA, VA 22314			GILBERT, SAMUEL G	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/645,869	KOENIG ET AL.	
	Examiner	Art Unit	
	Samuel G. Gilbert	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,9-13,15,17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,9-13,15,17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 9-13, 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marmar et al. in view of Stewart (4,718,411).

Marmar teaches a method for treating a human male the male diagnosed with atherosclerosis as a primary cause of erectile dysfunction, on page 975, column 1 lines 21-23. At least some of the patients treated having vasculogenic diagnosis which included arterial obstruction, page 977, column 1 line 1. It is the examiner's position that a patient diagnosed with vascular obstructions and vasculogenic impotence would be diagnosed with atherosclerosis. The method includes injecting phentolamine mesylate and papaverine hydrochloride(a PDE-5 inhibitor), page 976 column 1 lines 2 and 3 and applying a vacuum constriction device to achieve an erection(the combined method is used after failure of injections alone, page 975 column 2 lines 30-40). The method includes using a constriction ring during the procedure. However, for at least some of the patients the erection was maintained after the constriction device was removed. It is old and well known in the medical arts that a vacuum constriction device comprises two elements, the first being a tube for generating a vacuum for inducing an erection and a constriction ring for maintaining the erection after the vacuum tube is

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removed. It is further, known in the medical arts that the use of a constriction ring is only needed when the erection cannot be maintained without the use of the constriction ring. The applicant's attention is invited to column 1 lines 1-26 of Stewart. It would have been obvious to one of ordinary skill in the art at the time the invention was made to used the method of Marmar without the use of a constriction ring at least for those patients where the erection is maintained without the use of the constriction ring because it is well known in the medical arts that a vacuum device can be used with or without the use of a constriction ring as taught by Stewart.

Claim 5 – no adverse side effects are set forth with the use of papaverine hydrochloride.

Claims 9 and 10 – the use of phentolamine mesylate and papaverine hydrochloride(a PDE-5 inhibitor) is set forth.

Claim 11 – no adverse side effects are set forth with the use of phentolamine mesylate and papaverine hydrochloride.

Claims 12 and 13 – it is the examiner's position that periodic and regular use of the method will inherently achieve natural erections, page 938 column 2 lines 4-11 teach that combined use may be limited to twice per week, which would be periodic and regular.

Claims 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marmar and Stewart as applied to claim 1 above, and further in view of Podolski (6,482,426).

Claim 15 – combination of Marmar and Stewart teaches a method as claimed but does not teach the use of Sildenafil citrate. Podolski teaches an injectable composition including α -adrenergic blocker(e.g. phentolamine mesylate), a phosphodiesterase inhibitor (e.g. papaverine hydrochloride or Sildenafil), and a prostaglandin (e.g. alprostadil). Therefore Sildenafil and papaverine hydrochloride are functional equivalents. It would have been obvious to one of ordinary skill to use Sildenafil in place of papaverine hydrochloride in the method of Marmar and Stewart as a substitution of functional equivalent elements.

Claims 17 and 18 – the combination of Marmar and Stewart the method uses a combination of phentolamine mesylate and papaverine hydrochloride for the injections. Podolski teaches a combination including an α -adrenergic blocker(e.g. phentolamine mesylate), a phosphodiesterase inhibitor (e.g. papaverine hydrochloride or Sildenafil), and a prostaglandin (e.g. alprostadil). The specific combination and ratios are selected to be a safe alternative and to minimize the drawbacks of therapies set forth in the “Background of the Invention” section of Podolski, applicant’s attention is invited to column 3 lines 20-22 of Podolski. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combination of an α -adrenergic blocker(e.g. phentolamine mesylate), a phosphodiesterase inhibitor (e.g.

Sildenafil), and a prostaglandin (e.g. alprostadil) as taught by Podolski in place of the combination taught by Marmar and Stewart to provide the benefits as set forth in Podolski.

Response to Arguments

Applicant's arguments with respect to claims 1, 5, 9-13, 15, 17 and 18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Samuel G. Gilbert
Primary Examiner
Art Unit 3736

SGG
8/26/2005